



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON,
DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

November 07, 2019

MEMORANDUM

Subject: Efficacy Review for Concrobium Mold Control; EPA File No. 82552-G; DP Barcode: D454099;
Submission #: 1036690; E-Sub # 40557.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Thao Pham, Acting Efficacy Team Leader
Product Science Branch
Antimicrobials Division (7510P)
Date signed: 11/20/19

To: Jacqueline Hardy RM 34/ Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Siamons International, Inc.
48 Galaxy Blvd., Unit 413
Toronto, Ontario M9W 6C8
Canada

Formulation from the Label:

Active Ingredients	% by wt.
Sodium Carbonate	1.005 %
Other Ingredients:	98.995 %
Total	100.000 %

I. BACKGROUND

Product Description (as packaged, as applied): Liquid RTU.

Submission type: New end use product

Currently registered efficacy claim(s): NA

Requested action(s): New product Registration

Documents considered in this review:

- Letter from applicant to EPA dated June 26, 2019
- Application for Pesticide (EPA form 8570-1) dated June 26, 2019
- Confidential Statement of Formula (EPA form 8570-4) dated June 26, 2019
- Certification with Respect to Citation of Data (EPA Form 8570-34) dated June 26, 2019
- Data Matrix (EPA Form 8570-35) dated June 26, 2019
- 5 efficacy studies (MRID nos. 501633-01 - 501633-09)
- Proposed label dated 05/26/2019.

II. PROPOSED DIRECTIONS FOR USE

[[Remove heavy soil prior to application] [Mold stains may remain visible following treatment] [This is normal] [In this case] [If so] [If mold stains remain] [following treatment] [reapply] [product] [and] [wipe] [or] [scrub] [area] [away stains] [In some cases, staining may be irreversible.] [[Do not expect] [Concrobium Mold Control [insert brand name] [this product] [to] [will not] [whiten] stains [on contact]]. [If, [following treatment], additional steps are taken to [remove] [or] [cover] [address] [treat] the [mold] stain, reapply [[Concrobium Mold Control [insert brand name] [this product]] as a final step [as] [per] [as indicated in] [the] [Preventative Treatment] [To Prevent] [of] [[mold] [and] [mildew] section] [to protect area from regrowth.]]

Apply [Concrobium Mold Control [insert brand name] [this product]] by cloth[,] [or] [sponge,], handspray, [electric or compression sprayer,] [paintbrush,] [roller,] [or immersion]. Expect 350-2800 sq. ft. of surface coverage per gallon depending on surface type [and application method].

[FOR CLEANING [AND] [DEGREASING]] {numbering of steps is optional}

- [1]] Apply [product] [Concrobium Mold Control [insert brand name]] on area until wet.
- [2]] Wipe [or scrub][Wipe/scrub] clean [and dry]. [No rinsing required.]
- [3]] [For tough stains, reapplication may be necessary.]

[PREVENTATIVE TREATMENT] [FOR] [TO PREVENT] [OF] [MOLD] [AND] [MILDEW]

To [inhibit] [prevent] mold and mildew growth on surfaces:

{numbering of steps is optional}

- [1]] Apply [product] [Concrobium Mold Control [insert brand name]] on area until evenly wet.
- [2]] [[If desired][If dry time][If water staining][is a] [potential] [concern] [To promote drying] [and] [to][avoid residue marks], [use a] [clean cloth] [or] [paper towel] [dampened with] [product] Concrobium Mold Control [insert brand name]] [to] [wipe] [off] [wipe off] [clean] [clean off] [off excess wetness] [with a clean cloth or paper towel].
- [3]] Allow treated surfaces to dry completely. [The product generally dries within 2 hours and may take up to 24 hours depending on surface absorbency, temperature and [drying] conditions.]
- [[4]] [If treated surfaces are to be [cleaned] [and] [/] [or] [painted], allow [product] [Concrobium Mold Control [insert brand name]] to dry for 24 hours.]

To Disinfect [and] [Kill Fungi [& Mildew]]: {numbering of steps is optional}

[1] Clean surfaces to remove visible soil.

[2] From a distance of 6-8", spray product on hard, nonporous surfaces until thoroughly wet. Allow to remain wet for 10 minutes.

[3] [Wipes surfaces] [and] [or] [allow to air dry].

III. STUDY SUMMARIES

1.	MRID	508217-11	Study Completion Date:		October 25, 2018		
Study Objective		Disinfectant – Bactericidal					
Testing Lab, Lab Study ID		Accuratus Lab Services, A25891					
Test organism(s) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442), <i>Salmonella enterica</i> (ATCC 10708), and <i>Staphylococcus aureus</i> (ATCC 6538)					
Test Method		AOAC Germicidal Spray Method, ACCURATUS Protocol # SIA001011018.GS (copy provided)					
Application Method		Carriers were individually sprayed 15 times (15 sprays) or until thoroughly wet at 30 centimeters					
Test Substance Preparation	Name/ID	CMC-Plus (Concrobium Mold Control)					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	Lot# SII-23022018-A, Lot# SII-23022018-B, and Lot# SII-23022018-C					
	Preparation	Conveniently diluted to the LCL with sterile deionized water					
Soil load		No soil load required					
Carrier type, # per lot		Glass slides, 60 per microorganism and per batch					
Test conditions		Contact time	9.5 min.	Temp	20-21°C	RH	46-55%
Neutralizer		Lethen Broth + 0.07% Lecithin + 0.5% Tween 80 + 0.1% Sodium Thiosulfate (20 ml)					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		<p>Carriers were each inoculated with 10.0 µL of culture using a calibrated pipettor. The carriers were allowed to dry for 30-31 minutes at 35-37°C (35.8-36.0°C) and at a 37.0 – 54.0% relative humidity and appeared visibly dry.</p> <p>Invalid data in Attachment I, due to population control results below the minimum acceptance criterion for <i>Pseudomonas aeruginosa</i>.</p> <p>The test substance was applied using 15 trigger sprays for testing. More information is needed to support this application.</p>					

2.	MRID	508217-12	Study Completion Date:		April 15, 2019	
Study Objective		Disinfectant – Fungicide				
Testing Lab, Lab Study ID		Microchem, GLP2071				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Trichophyton interdigitale</i> (ATCC 9533)				
Test Method		AOAC Germicidal Spray Products as Disinfectants Test - Microchem Laboratory Protocol # P2309 (copy provided)				
Application Method		Carriers were individually sprayed 15 times (15 sprays) from 6-8 inches away at approximately 45° from the test carrier to the spray nozzle.				
Test Substance Preparation	Name/ID	CMC-Plus (Concrobium Mold Control)				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	SII-18122018-B, SII-18122018-C				
	Preparation	Conveniently diluted to the LCL with sterile deionized water				
Soil load		No soil load required				
Carrier type, # per lot		Glass slides, 10 per microorganism and per batch				

Test conditions	Contact time	9min50sec.- 9min55 sec.	Temp	20.4-23.4°C	RH	-
Neutralizer	Sabouraud Dextrose Broth supplemented to contain 0.07% Lecithin and 0.5% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	<p>Carriers were each inoculated with 10.0 µL of culture and were allowed to dry for 30-31 minutes at 35-37°C until visibly dry.</p> <p>Protocol was amended to add a test with an increased contact time. After failure at 9 minutes 50 seconds contact time, lot SII-18122018-C was tested using a 9 minute 55 second exposure time.</p> <p>The test substance was applied using 15 trigger sprays for testing. More information is needed to support this application.</p>					

3.	MRID	508217-13	Study Completion Date:			April 23, 2019	
Study Objective		Disinfectant – Fungicide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A25595					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Aspergillus niger (ATCC 6275)					
Test Method		Fungicidal Germicidal Spray Method – Accuratus Lab Services Protocol # SIA001011018.FGS.1 (copy provided)					
Application Method		Carriers were individually sprayed 15 times (15 sprays) from 30 centimeters away, at in an undisturbed horizontal position.					
Test Substance Preparation	Name/ID	CMC-Plus (Concrobium Mold Control)					
	Lots ☐ 1 ☒ 2 ☐ 3	Lot# SII-23022018-A and Lot# SII-23022018-B					
	Preparation	Conveniently diluted to the LCL with sterile deionized water					
Soil load		No soil load required					
Carrier type, # per lot		Glass slides, 10 per microorganism and per batch					
Test conditions		Contact time	9.50 min. 9min45 sec.	Temp	20-21°C	RH	48-51%
Neutralizer		-					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were each inoculated with 10.0 µL of culture and were allowed to dry for 30-31 minutes at 36.1-36.2°C under and at a 43-51.7% relative humidity, until visibly dry. Protocol was amended to add an additional test substance parameter. After failure at 9.5 minutes contact time, lot SII-23022018-A was tested using a 9 minute 45 second exposure time. The test substance was applied using 15 trigger sprays for testing. More information is needed to support this application.					

4.	MRID	508217-14	Study Completion Date:	October 10, 2018
Study Objective		Hard Surface Mildew Fungistatic		
Testing Lab, Lab Study ID		Accuratus Lab Services, A25877		
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Aspergillus niger (ATCC 6275)		
Test Method		EPA Hard Surface Mildew-Fungistatic Test – Accuratus Lab Services Protocol # SIA001011018.MSTAT (copy provided)		
Application Method		Carriers were individually sprayed 15 times (15 sprays) from 30 centimeter away, in a vertical or near vertical position to permit excess liquid to drain.		
Test Substance Preparation	Name/ID	CMC-Plus (Concrobium Mold Control)		
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Lot# SII-23022018-B and Lot# SII-23022018-C		

	Preparation	Conveniently diluted to the LCL with sterile deionized water				
Soil load		No soil load required				
Carrier type, # per lot		One inch by one inch glazed ceramic tiles, 10 per microorganism and per batch				
Test conditions		Contact time	-	Temp	=	RH
Neutralizer		-				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were dried for 20 minutes at 35.8-36.1°C under and at a 32% relative humidity				
		Carriers were each inoculated with 3 sprays of culture and were allowed to dry for 26 minutes at 36.1-36.2°C under and at a 28.7% relative humidity, until visibly dry.				
		Each carrier (contaminated side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 29.0°C in a minimum of 95% relative humidity.				
		The test substance was applied using 15 trigger sprays for testing. More information is needed to support this application.				

5.	MRID	508217-15	Study Completion Date:			October 10, 2018		
Study Objective		Fabric Mildew Fungistatic						
Testing Lab, Lab Study ID		Accuratus Lab Services, A25876						
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Aspergillus niger (ATCC 6275) and Penicillium variable (ATCC 32333)						
Test Method		Fabric Mildew Fungistatic Test – Accuratus Lab Services Protocol # SIA001011018.FMSTAT (copy provided)						
Application Method		Each side of carriers was sprayed 15 times (15 sprays) from 30 centimeter away, in a vertical or near vertical position to permit excess liquid to drain.						
Test Substance Preparation	Name/ID	CMC-Plus (Concrobium Mold Control)						
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	Lot# SII-23022018-B and Lot# SII-23022018-C						
	Preparation	Conveniently diluted to the LCL with sterile deionized water						
Soil load		No soil load required						
Carrier type, # per lot		Fabric carriers (25 mm by 75 mm strips from 136 to 203 g/m ² (4 to 6 oz/yd ²) cotton muslin, 10 of mixed microorganisms per batch						
Test conditions		Contact time	-	Temp	=	RH	-	
Neutralizer		Sabouraud Dextrose Broth + 0.07% Lecithin and 0.5% Tween 80						
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		The carriers were dried at room temperature (22.1°C) for 30 minutes until dry.						
		Each side of carrier was inoculated with 3 sprays of mixed inocula (for a total of 6 sprays per carrier).						
		Each contaminated carrier was suspended in individual 250 ml French Square bottles containing approximately 10 ml sterile deionized water (for humidity) and incubated at 29.0°C. Observations were made and recorded every 7 days for four weeks.						

V. RESULTS

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average log ₁₀ /Carrier
		SII-23022018-A	SII-23022018-B	SII-23022018-C	
Diluted to the LCL and 9.5 minutes contact time – No soil load					

MRID (Test Date)	Organism	No. Exhibiting Growth/Total No. Tested			Average log ₁₀ /Carrier
		SII-23022018-A	SII-23022018-B	SII-23022018-C	
508217-11	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	0/60	5.45
	<i>Salmonella enterica</i> (ATCC 10708)	0/60	0/60	0/60	5.62
	<i>Staphylococcus aureus</i> (ATCC 6538)	0/60	0/60	0/60	5.56
Diluted to the LCL - 9.5 minutes and 9 minutes 45 seconds contact time – No soil load					
508217-13	<i>Aspergillus niger</i> (ATCC 6275)	0/10	0/10	-	4.35 / 4.37
		SII-18122018-B	SII-18122018-C	-	
Diluted to the LCL - 9 minutes 50 seconds and 9 minutes 55 seconds contact time – No soil load					
508217-12	<i>Trichophyton interdigitale</i> (ATCC 9533)	0/10	0/10	-	4.02 / 4.39

MRID # 508217-14	Carrier Number	Visual Evaluation of Controls	7 Days Evaluation Lot SII-23022018-B		7 Days Evaluation Lot SII-23022018-C	
			Visual	Magnified	Visual	Magnified
<i>Aspergillus niger</i> (ATCC 6275)	1	Growth (80%)	0%	No growth	0%	No growth
	2	Growth (80%)	0%	No growth	0%	No growth
	3	Growth (80%)	0%	No growth	0%	No growth
	4	Growth (70%)	0%	No growth	0%	No growth
	5	Growth (80%)	0%	No growth	0%	No growth
	6	Growth (80%)	0%	No growth	0%	No growth
	7	Growth (80%)	0%	No growth	0%	No growth
	8	Growth (80%)	0%	No growth	0%	No growth
	9	Growth (90%)	0%	No growth	0%	No growth
	10	Growth (90%)	0%	No growth	0%	No growth

MRID # 508217-15	Carrier Number	Visual Evaluation of Controls	7 Days Evaluation Lot SII-23022018-B		7 Days Evaluation Lot SII-23022018-C	
			Visual	Magnified	Visual	Magnified
Mixed 50/50 <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)	1	Growth (80%)	0%	No growth	0%	No growth
	2	Growth (80%)	0%	No growth	0%	No growth
	3	Growth (80%)	0%	No growth	0%	No growth
	4	Growth (70%)	0%	No growth	0%	No growth
	5	Growth (80%)	0%	No growth	0%	No growth
	6	Growth (80%)	0%	No growth	0%	No growth
	7	Growth (80%)	0%	No growth	0%	No growth
	8	Growth (80%)	0%	No growth	0%	No growth
	9	Growth (90%)	0%	No growth	0%	No growth
	10	Growth (90%)	0%	No growth	0%	No growth

MRID # 508217-15	Carrier Number	Visual Evaluation of Controls (% Coverage)			
		Day 7	Day 14	Day 21	Day 28
Mixed 50/50 <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)	1	Growth (60%)	Growth (65%)	Growth (75%)	Growth (100%)
	2	Growth (50%)	Growth (55%)	Growth (60%)	Growth (85%)
	3	Growth (50%)	Growth (60%)	Growth (70%)	Growth (100%)
	4	Growth (50%)	Growth (55%)	Growth (60%)	Growth (80%)
	5	Growth (50%)	Growth (60%)	Growth 75%)	Growth (85%)
	6	Growth (50%)	Growth (55%)	Growth (65%)	Growth (100%)

	7	Growth (50%)	Growth (50%)	Growth (60%)	Growth (100%)
	8	Growth (55%)	Growth (55%)	Growth (60%)	Growth (75%)
	9	Growth (50%)	Growth (50%)	Growth (60%)	Growth (100%)
	10	Growth (50%)	Growth (60%)	Growth (70%)	Growth (100%)

MRID # 508217- 15	Carrier Number	Mixed 50/50 <i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)							
		Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
Evaluation of treatment Lot SII- 23022018- B	1	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	2	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	3	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	4	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	5	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	6	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	7	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	8	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	9	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	10	0%	No growth	0%	No growth	0%	No growth	0%	No growth
Evaluation of treatment Lot SII- 23022018- C	1	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	2	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	3	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	4	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	5	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	6	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	7	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	8	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	9	0%	No growth	0%	No growth	0%	No growth	0%	No growth
	10	0%	No growth	0%	No growth	0%	No growth	0%	No growth

VI. CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
508217-11	Disinfectant Bactericidal	Hard, non-porous surfaces	15 Sprays LCL	10 minutes	No	No	<i>Staphylococcus aureus</i> (ATCC 6538) <i>Salmonella enterica</i> (ATCC 10708) <i>Pseudomonas aeruginosa</i> (ATCC 15442)	No
508217-12 508217-13	Disinfectant Fungicide	Hard, non-porous surfaces	15 Sprays LCL	10 minutes	No	No	<i>Trichophyton interdigitale</i> (ATCC 9533) <i>Aspergillus niger</i> (ATCC 6275)	No
508217-14	7days Hard Surface Mildew Fungistatic	Hard, non-porous surfaces	15 Sprays LCL	-	No	No	<i>Aspergillus niger</i> (ATCC 6275)	No
508217-15	Fabric Mildew Fungistatic	Fabric	15 Sprays LCL	-	No	No	<i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)	Yes

VII. LABEL COMMENTS

Proposed Label dated 05/26/2019

Note: Please change nominal label concentrations to match the CSF.

1. Spray products are usually tested using 2 to 3 sprays; spraying 15 times is not representative of how a typical user would apply the product to a hard surface. More information is needed to support this excessive number of sprays, including a description of the applicator and total volume of product released from 15 sprays. Until this information is submitted and reviewed by this agency, the following claims should be removed from the label:
 - a. The proposed label claims that the product, Concrobium Mold Control (EPA File No. 82552-G), is an effective bacterial disinfectant spray, when used undiluted, at room temperature, for 10 minutes, on pre-cleaned hard, non-porous surfaces; these claims **are unacceptable**.
 - b. The proposed label claims that the product, Concrobium Mold Control (EPA File No. 82552-G), is an effective fungicide disinfectant spray, when used undiluted, at room temperature, for 10 minutes, on pre-cleaned hard, non-porous surfaces; these claims **are unacceptable**.
 - c. The proposed label claims that the product, Concrobium Mold Control (EPA File No. 82552-G), is an effective mildew disinfectant spray, when used undiluted, at room temperature, for 10 minutes, on pre-cleaned hard, non-porous surfaces; these claims **are unacceptable**.
 - d. The proposed label claims that the product, Concrobium Mold Control (EPA File No. 82552-G), is an effective mildew fungistat spray, when used undiluted, at room temperature, on cleaned hard, non-porous surfaces; these claims **are unacceptable**. Note, for future reference, these label claims should be clearly limited to 7 days.
2. The proposed label claims that the product, Concrobium Mold Control (EPA File No. 82552-G), is an effective mildew fungistat spray, when used undiluted, at room temperature, on clean fabric; these claims **are acceptable**.
3. The product, Concrobium Mold Control (EPA File No. 82552-G) is a spray only product. Application by mop, sponge, or cloth is not acceptable.
4. Make the following changes to the proposed label:
 - a. Throughout the label, remove all public health claims including: disinfection, mildewcidal, fungicidal, bactericidal, mildewcide, kill(s), eliminate(s), one-step.
 - b. Remove all claims for treatment of mold including: control, inhibit, prevent, fight, defend, eradicate, abolish, destroy, crush, attack, get rid of, remediate, lethal for mold, conquer, encapsulates, tough on mold, fungal spores, etc.
 - c. Remove all claims for hard nonporous surfaces or multiple surface types. The only acceptable claim is to control mildew on clean fabric.
 - d. Remove all "2 in 1", "2 for 1", "3 in 1", "3 for 1" and "all in one" claims.
 - e. Product was tested as a spray. Remove directions for use for other application types.
 - f. Remove mold remediation language.
 - g. Revise use directions to remove public health claims and specify treatment as a mildewstat for fabrics.